Clinical Policy Bulletin: Electrical Stimulation for Xerostomia

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Policy

Aetna considers electrical stimulation (e.g., the Salitron System and the Saliwell Crown device) experimental and investigational for the prevention or treatment of xerostomia (dry mouth) or for any other indications because its effectiveness has not been established.

Background

Chronic xerostomia can be caused by Sjogren's syndrome, certain medications or therapeutic irradiation. It can cause difficulty in eating dry foods, swallowing and wearing dentures; and susceptibility to dental caries, oral pain and frequent infections. Proponents of electrostimulation as a treatment option postulate that stimulating the tongue and the roof of the mouth simultaneously will result in impulses to all residual salivary tissues, major and minor, in the oral and pharyngeal regions, thus causing salivation.

Although the Food and Drug Administration (FDA) approved the Salitron System in 1988 to treat xerostomia secondary to Sjogren's syndrome, the Agency for Health Care Policy and Research (AHCPR) advised in a 1991 assessment that there were “insufficient data to determine the clinical effectiveness of this modality of salivary production, or to identify those xerostomic patients who would benefit from the procedure” (Erlichman, 1991). One published study (Weiss et al, 1986) reported some degree of response after 3 stimulation sessions of 3 minutes each in 24 patients with xerostomia related to Sjogren's, radiation therapy, drugs or unknown etiology. However, there was no control group, information on the duration of response, quantitative assessment of salivary response, or intermediate or long-term assessment of effectiveness.

Another report, a double-blind study (Steller et al, 1988) noted a statistically significant mean increase in post-stimulation whole saliva

flow between subjects (n = 29) using active and placebo stimulators. However, this was due mainly to the responses of 3 subjects who showed marked increases in their whole saliva flow rate during the study. Of the active study arm, only 1 subject showed evidence of a cumulative response over the 4 weeks of the study. Further research of electrical stimulation of salivary flow is needed to ascertain its role in the treatment of Sjogren's patients with xerostomia.

Talal and colleagues (1992) reported that electrical stimulation improves salivary function of patients with Sjogren's syndrome. In this placebo controlled study, patients received three treatments (2 weeks apart, over a 4-week period) with an active device (n = 34) or a placebo device (n = 37). Patients using active devices showed a statistically greater increase in salivary production than patients using placebo devices. Moreover, patients demonstrated significant improvement in other symptoms such as difficulty in swallowing as well as burning tongue. The major shortcomings of this study were (i) it is unclear whether the control group was age-matched, (ii) lack of long-term assessment of effectiveness, and (iii) the number of patients in the active device group who did not respond to treatment was not disclosed, and the range or standard deviation for pre- and post-stimulation whole salivary flow rates was not given.

The role of electrical stimulation in the management of patients with xerostomia awaits the outcomes of randomized, double-blind, controlled clinical studies with large sample sizes and long-term follow-up. In many reviews on the management of patients with xerostomia (Cooke, 1996; Fox, 1997; Davies, 1997; Mariette, 2002; Fox, 2003), salivary electrostimulation was not mentioned as a method to manage patients with this condition.

Strietzel et al (2007) evaluated the safety and effectiveness of a recently developed electro-stimulating device mounted on an individualized intra-oral removable appliance. The device, containing electrodes, a wetness sensor, an electronic circuit and a power source, was tested on patients with xerostomia in a cross-over, randomized, sham-controlled, double-blinded, multi-center study (n = 23; 10 with primary Sjogren's syndrome, 7 with medication-induced xerostomia, and 6 with idiopathic xerostomia). Electrical stimulation and also sham were delivered for 10 mins to the oral mucosa, in the mandibular third molar region. Oral dryness was measured by the sensor. As the primary outcome, sensor dryness and xerostomia symptom changes as a result of device wearing were assessed, and compared between active and sham modes. In addition, side-effects were recorded. Electro-stimulation resulted in a significant decrease in sensor dryness, leading to a beneficial effect on patients' subjective condition. No significant adverse events were observed. However, 30.4 % patients reported the sham mode to be more effective than the

active mode. The authors stated that these findings are encouraging enough to continue developing and investigating the miniature electrostimulating device mounted on a dental implant.

In a preliminary study, Ami and Wolff (2010) evaluated the effect on xerostomia of the Saliwell Crown (Saliwell Ltd., Harutzim, Israel), an innovative saliva electrostimulation device fixed on an implant, placed in the lower third molar area. A Saliwell Crown was placed in the lower third molar area of an 81-year old female patient with complaints of dry and burning mouth. Salivary secretion was measured, and the patient was asked to fill in written satisfaction questionnaires. The patient was monitored for 1 year, comparing her salivary secretion rates and the written questionnaires. The results showed a constant slight but significant increase in the salivary secretion and in the patient's personal feelings as presented in the questionnaires. The authors concluded that the saliva stimulation device Saliwell Crown, placed on an implant in an 81-year old patient with dry and burning mouth complaints, presented promising results when both the salivary secretion tests and the self-assessment questionnaires were examined and compared. The findings of this case study need to be validated by well-designed studies.

Strietzel and colleagues (2011) evaluated the safety and effectiveness of an intra-oral electrostimulation device, consisting of stimulating electrodes, an electronic circuit, and a power source, in treating xerostomia. The device delivers electrostimulation through the oral mucosa to the lingual nerve in order to enhance the salivary reflex. The device was tested on a sample of patients with xerostomia due to Sjogren's syndrome and other sicca conditions in a 2-stage prospective, randomized, multi-center trial. Stage I was a double-blind, cross-over stage designed to compare the effects of the electrically active device with the sham device, each used for 1 month, and stage II was a 3-month open-label stage designed to assess the long-term effects of the active device. Improvement in xerostomia severity from baseline was the primary outcome measure. A total of 114 patients were randomized. In stage I, the active device performed better than the sham device for patient-reported xerostomia severity ($p < 0.002$), xerostomia frequency ($p < 0.05$), quality of life impairment ($p < 0.01$), and swallowing difficulty ($p < 0.02$). At the end of stage II, statistically significant improvements were verified for patient-reported xerostomia severity ($p < 0.0001$), xerostomia frequency ($p < 0.0001$), oral discomfort ($p < 0.001$), speech difficulty ($p < 0.02$), sleeping difficulty ($p < 0.001$), and resting salivary flow rate ($p < 0.01$). The authors concluded that the results indicated that daily use of the device alleviated oral dryness, discomfort, and some complications of xerostomia, such as speech and sleeping difficulties, and increased salivary output. These findings need to be verified by additional research.

Fedele et al (2010) noted that xerostomia is a very common condition, which not only involves dry mouth feeling, but can also lead to psychosocial distress, impaired quality of life, and complications, such as dental caries and oral candidiasis. It is generally induced by hypofunction of salivary glands, which has a wide variety of etiologies, such as Sjogren's syndrome, radiotherapy to the head and neck and side effects of medications. Current therapies rely on saliva substitutes and pharmacological stimulation of the parasympathetic system. These treatment modalities are somewhat limited by their short-term efficacy, high cost and drug interactions or other adverse effects. Local transcutaneous or per-mucosal electrostimulation in areas close to the nerves participating in the salivary autonomic reflex has been found to increase salivary secretion in animal and clinical experiments and to relieve symptoms of dry mouth in patients with salivary gland hypofunction. These investigators reviewed the current status and potential of intra-oral miniature electrostimulating devices. The authors stated that these intra-oral electrostimulating devices offer promise as an optional safe and non-chemical treatment of xerostomia.

In a phase II randomized, controlled study, Wong et al (2010) examined the potential effectiveness of xerostomia prevention using acupuncture-like transcutaneous electrical nerve stimulation (ALTENS) delivered concomitantly with radiotherapy administered to head and neck cancer patients. A total of 60 patients were randomized to either the treatment group (n = 30) that received ALTENS daily with radiotherapy or the control group (n = 26) that had standard mouth care only. Stimulated and basal unstimulated whole saliva production (WSP) plus radiation-induced xerostomia (RIX) symptoms visual analog score (RIXVAS) were assessed at specific time points. Generalized linear models and generalized estimating equations were used for analysis. RIXVAS at 3 months follow-up after therapy completion was used as the primary study endpoint. The mean RIXVAS for the ALTENS intervention at 3 months was 39.8, which was not significantly different from the control arm value of 40.5. There were no statistically significant differences between the 2 groups for their mean RIXVAS and WSP at all assessment time points. The authors concluded that there was no significant difference in mean WSP and RIXVAS between the 2 groups, so ALTENS is not recommended as a prophylactic intervention.

In a phase II component of a multi-institutional, phase II/III, randomized trial, Wong et al (2012) evaluated the feasibility and preliminary effectiveness of ALTENS in reducing radiation-induced xerostomia. Patients with cancer of the head and neck who were 3 to 24 months from completing radiotherapy with or without chemotherapy (RT +/- C) and who were experiencing xerostomia symptoms with basal whole saliva production greater than or equal to 0.1 ml/min and were without recurrence were eligible. Patients received twice-weekly ALTENS sessions (24 sessions over 12 weeks) using a proprietary

electrical stimulation unit. The primary study objective was to assess the feasibility of ALTENS treatment. Patients were considered compliant if 19 of 24 ALTENS sessions were delivered, and the targeted compliance rate was 85 %. Secondary objectives measured treatment-related toxicities and the effect of ALTENS on overall radiation-induced xerostomia burden using the University of Michigan Xerostomia-Related Quality of Life Scale (XeQOLS). Of 48 accrued patients, 47 were evaluable. The median age was 60 years, 84 % of patients were men, 70 % completed RT +/- C for greater than 12 months, and 21 % had previously received pilocarpine. Thirty-four patients completed all 24 ALTENS sessions, 9 patients completed 20 to 23 sessions, and 1 patient completed 19 sessions, representing a 94 % total compliance rate. Six-month XeQOLS scores were available for 35 patients and indicated that 30 patients (86 %) achieved a positive treatment response with a mean +/- standard deviation reduction of 35.9 % +/- 36.1 %. Five patients developed grade 1 or 2 gastro-intestinal toxicity, and 1 had a grade 1 pain event. The authors concluded that the current results indicated that ALTENS treatment for radiation-induced xerostomia can be delivered uniformly in a cooperative, multi-center setting and produced possible beneficial treatment response. They noted that given these results, the phase III component of this study was initiated.

CPT Codes / HCPCS Codes / ICD-9 Codes

HCPCS codes not covered for indications listed in the CPB:

E0755	Electronic salivary reflex stimulator (intraoral/noninvasive)

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

521.00 - 521.09	Dental caries
527.7	Disturbance of salivary secretion (xerostomia)
528.9	Other and unspecified diseases of oral soft tissues
710.2	Sicca syndrome [Sjogren's disease]
787.2	Dysphagia

990	Effects of radiation, unspecified [radiation-induced xerostomia]
V15.3	Personal history of irradiation

The above policy is based on the following references:

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15. Wong RK, James JL, Sagar S, et al. Phase 2 results from Radiation Therapy Oncology Group Study 0537: A phase 2/3 study comparing acupuncture-like transcutaneous electrical nerve stimulation versus pilocarpine in treating early radiation-induced xerostomia. Cancer. 2012;118(17):4244-4252.

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Electrical stimulation of post-irradiated head and neck squamous cell carcinoma to improve xerostomia.

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Abstract

OBJECTIVE:
We observed a significant improvement in the complaints of dysphagia in patients with head and neck cancer who had received noninvasive neuromuscular electrical stimulation (E-stim) of their pharyngeal muscles. We wanted to determine if the improvement in dysphagia was a result of decreased complaints of xerostomia and increased saliva production, since one of our first patients being treated with E-stim noticed a significant improvement in xerostomia.

STUDY DESIGN:
Prospective trial to determine the effects of E-stim by evaluating saliva production and dysphagia questionnaires instituted by our speech pathologists on head and neck cancer patients that had received radiotherapy (XRT) and were to undergo E-stim for dysphagia.

METHODS:
Prior to the initiation of E-stim and one to two months after E-stim, saliva samples were collected and patients were asked to answer a Dysphagia and Xerostomia Index Questionnaire. All patients received E-stim two to four months after completing XRT. Patients received three E-stim treatments per week for a total of one to two months. Four electrodes were placed along anterior neck over pharyngeal muscles. E-stim was initiated using four to 30mA at 80-100 pulse-widths.

RESULTS:
Five patients that received either postoperative radiation therapy or concomitant chemoradiotherapy had been treated with E-stim. All five patients noticed a significant improvement in dysphagia. Five out of five patients noticed a definite increase in saliva production with symptoms of decreased intake of water with meals, sleeping longer hours at night, and increased moistness of lips.

CONCLUSION:

E-stim therapy appears to be an effective and approved treatment for dysphagia. Our study shows that it may also be beneficial for xerostomia in the post-irradiated head and neck cancer patients.

SIGNIFICANCE:
To determine if E-stim will benefit the previously irradiated patient with dysphagia and xerostomia.